

# APO-Lamotrigine

contains the active ingredient Lamotrigine

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## Consumer Medicine Information

**For a copy of a large print leaflet Ph: 1800 195 055**

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### What is in this leaflet

**Read this leaflet carefully before taking your medicine.**

This leaflet answers some common questions about lamotrigine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

**Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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### What this medicine is used for

The name of your medicine is APO-Lamotrigine. It contains the active ingredient lamotrigine.

It is used to treat epilepsy in adults and children.

Lamotrigine is used in partial seizures (seizures that affect only one part of the brain) or generalised seizures (seizures that affect the whole brain) including Lennox-Gastaut Syndrome (a severe form of epilepsy characterised by several seizure types).

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

### How it works

Lamotrigine belongs to a group of medicines called "anti-epileptic drugs".

Lamotrigine is often used in combination with other antiepileptic medicines.

There is no evidence that this medicine is addictive.

### Use in children

This medicine may be used to treat epilepsy in children 2 years of age and over.

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### Before you take this medicine

#### **When you must not take it**

**Do not take this medicine if:**

- **You are pregnant.**

Lamotrigine may affect your unborn baby if you take it during pregnancy.

Your doctor will discuss the risks and benefits of taking lamotrigine during pregnancy and help you decide whether or not you should take it.

It is recommended that women on antiepileptic drugs, including lamotrigine receive pre-pregnancy counselling regarding the risk to their unborn child.

Studies have shown that lamotrigine can decrease the levels of folic acid during pregnancy. It is therefore recommended that you take a folate supplement before becoming pregnant and during the first 12 weeks of your pregnancy.

- **You are breast-feeding.**

Lamotrigine may pass into breast milk. Your doctor will discuss the risks and benefits of using lamotrigine tablets if you are breastfeeding.

- It has passed the expiry date (EXP) printed on the pack.
- The packaging is torn, shows signs of tampering or it does not look quite right.

- **You have had an allergic reaction to lamotrigine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, itching or hives on the skin.

**If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

### ***Before you start to take it***

#### **Tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - kidney disease
  - liver disease.
3. You are currently pregnant or breastfeeding or you plan to become pregnant or breast-feed.
4. You are planning to have surgery.
5. You are currently receiving or are planning to receive dental treatment.
6. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with lamotrigine. These include:

- sodium valproate ("Epilim", "Valpro"), used to treat epilepsy
- any form of hormonal contraception (e.g. "the pill")
- other anti-epileptic drugs including carbamazepine, phenobarbitone and primidone

- rifampicin, which is often used to treat infections including tuberculosis
- a combination of lopinavir and ritonavir, which is used to treat Human Immunodeficiency Virus (HIV) infection.
- risperidone, which is used to treat schizophrenia and bipolar disorder. You may be more likely to feel sleepy or drowsy if you take risperidone and lamotrigine together.

If you are taking any of these medicines you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with lamotrigine.

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## **How to take this medicine**

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Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

### ***How much to take***

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Usually your doctor will prescribe a low dose to start and gradually increase the dose during the first few weeks of treatment. The dose that your doctor prescribes will often depend on other anti-epileptic medications you are taking and your response to lamotrigine.

### **Hormonal Contraceptives:**

If you start or stop taking hormonal contraceptives (e.g. "the pill") while taking lamotrigine your doctor may need to adjust the dose of lamotrigine depending on how well your condition is being treated.

You should tell your doctor if there are any changes in your menstrual pattern such as breakthrough bleeding.

If you become pregnant your doctor may need to change your dose of lamotrigine or switch you to a different medicine.

### ***Use in children***

The dosage for children usually depends on their weight. Children's weight should be checked and the dose reviewed as weight changes occur.

### ***How to take it***

The tablets may be swallowed whole, chewed or dispersed in a glass of water (at least enough water to dissolve the whole tablet).

### ***When to take it***

Take this medicine at the same time each day. Taking your medicine at the same time each day will have the best effect and it will also help you remember when to take it.

### ***How long to take it for***

Continue taking your medicine for as long as your doctor tells you to.

Make sure you have enough to last over weekends and holidays.

Do not stop taking your tablets or change the dose without first checking with your doctor.

### ***If you forget to take it***

**Contact your doctor immediately if you have forgotten to take your dose of lamotrigine. Do not take a double dose to make up for the dose that you missed.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

### ***If you take too much (Overdose)***

**If you think that you or anyone else may have taken too much of**

**this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## **While you are taking this medicine**

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Your doctor or pharmacist will tell you if there are any special instructions while you are taking lamotrigine tablets.

### ***Things you must do***

**If you develop any skin rash (e.g. hives or spots) while being treated with lamotrigine, contact your doctor immediately.**

There are reports of skin rash associated with lamotrigine treatment. Skin rash can potentially be serious and cause severe illness.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery.

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

**Tell your doctor if you become pregnant or are trying to become pregnant.**

Tell your doctor if you are female and your menstrual periods change.

**Tell your doctor if you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**If you or someone you know is demonstrating any of the following warning signs of suicide while taking lamotrigine, contact your doctor right away or go to the nearest hospital for treatment:**

- thoughts or talk of death or suicide
- thoughts or talk of self-harm
- any recent suicide attempts or attempts at self-harm.

All mentions of suicide or violence must be taken seriously.

**Go to your doctor regularly for a check-up.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

### ***Things you must not do***

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Take any other prescription to non-prescription medicines without first telling your doctor.

**Do not stop taking lamotrigine or change the dose because you are feeling better.**

If you stop taking lamotrigine tablets abruptly your epilepsy may worsen or come back. This is known as "rebound seizures".

**Your doctor will advise you if you need to stop taking lamotrigine and, if so, how to do this safely. If you are unsure whether you should stop taking lamotrigine talk to your doctor or pharmacist.**

### ***Things to be careful of***

**If you develop any skin rash during lamotrigine treatment, contact your doctor immediately.**

There have been reports of skin rash associated with treatment. Some of these rashes may be serious and can cause severe illness.

**Treatment with antiepileptic medicines can increase your risk of suicidal thoughts and behaviour.**

This can occur early as 1 week after starting treatment. However suicidal thoughts and actions can also be from other causes.

Pay close attention to any day-to-day changes in mood, behaviour and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.

Be aware of common warning signs of suicidal behaviour such as:

- talking or thinking about wanting to hurt yourself or end your life
- becoming preoccupied with death and dying
- becoming depressed or experiencing worsening depression
- withdrawing from friends and family
- giving away prized possessions.

If any of the above happens seek medical advice immediately.

**Be careful driving or operating machinery until you know how lamotrigine affects you.**

Lamotrigine may cause dizziness and drowsiness, and affect alertness in some people.

Make sure you know how lamotrigine affects you before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, your dizziness or light-headedness may be worse. If any of these effects do not go away or are troublesome you should see your doctor.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.

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## Possible side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking lamotrigine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor or pharmacist if you notice any of the following and they worry you.**

This list includes the more common side effects. Mostly, these are mild:

- dizziness/unsteadiness
- headache
- drowsiness
- feeling sick ( nausea)
- vomiting
- feeling weak
- double vision
- blurred vision
- shaking
- trouble sleeping
- loss of memory
- confusion
- irritability/aggression
- agitation
- increased activity in children
- joint or back pain
- depression.

These side effects are more likely during the first few weeks of treatment. If any of these side effects persist, or are troublesome, see your doctor.

**If you experience any of the following, stop taking your medicine and contact your doctor**

**immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- any skin reactions or rash
- swelling of the face, lips or tongue
- sore mouth or sore eyes
- high temperature (fever)
- swollen glands
- drowsiness
- easy bruising or unusual bleeding
- yellow skin (jaundice).

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking lamotrigine.

**If you develop any skin rash during treatment with lamotrigine, contact your doctor immediately as you may need to stop taking lamotrigine. There are reports of serious skin rash with lamotrigine that may need hospital treatment. Very rarely serious skin rash may cause death.**

Another rare side effect is "Lupus-like reactions" which can cause symptoms such as fever, pain in the joints and general ill health.

Lamotrigine can sometimes cause you to experience more seizures than usual. Tell your doctor as soon as possible if your seizures get worse or if you have a different type of seizure.

### **Allergic reactions**

**If you think you are having an allergic reaction to lamotrigine, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.

- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

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## Storage and disposal

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### **Storage**

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees Celsius.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### **What APO-Lamotrigine looks like**

APO-Lamotrigine 25 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI2" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 50 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI3" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 100 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI4" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 200 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI5" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine tablets are available in blister packs of 56 tablets.

### ***Ingredients***

Each tablet contains lamotrigine as the active ingredient.

It also contains the following inactive ingredients:

- calcium carbonate
- aspartame
- microcrystalline cellulose
- crospovidone
- hydroxypropylcellulose
- magnesium stearate
- povidone
- colloidal anhydrous silica
- purified talc
- Cal-Carb 4450PG
- mixed berries 501161 AP0551.

This medicine is gluten-free, lactose-free, tartrazine-free and free of other azo dyes.

### ***Australian Registration Numbers***

APO-Lamotrigine 25 mg

(blister pack): AUST R 167520.

APO-Lamotrigine 50 mg

(blister pack): AUST R 167521.

APO-Lamotrigine 100 mg

(blister pack): AUST R 167523.

APO- Lamotrigine 200 mg

(blister pack): AUST R 167524.

### ***Sponsor***

Apotex Pty Ltd

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Australia

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